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Consumer Care Division

January 22, 1999

Gary S. Belkema
President
Region Head Northern Americas

Mr. Nicholas P. Reuter
Office of Health Affairs (HFY-20)
Food and Drug Administration (FDA)
5600 Fishers Lane
Rockville, MD 20857

RE: International Drug Scheduling; Convention on Psychotropic Substances;
Single Convention on Narcotic Drugs; WHO Scheduling Recommendations
for Ephedrine, Dihydroetorphine, Remifentanyl, and Certain Isomers
- Docket No. 98N-0148

Dear Mr. Reuter:

I am the President of Bayer Corporation, Consumer Care Division (Bayer) one of the nation's leading over-the-counter health care businesses. Bayer is known for brands such as Bayer Aspirin®, Aleve®, Alka-Seltzer®, Femstat 3® and Flintstones® and One-A-Day Vitamins®.

On behalf of Bayer, I am writing to request a public meeting concerning issues raised in the FDA's January 11, 1999 Federal Register notice regarding the World Health Organization's (WHO) recommendation that ephedrine be scheduled under the UN Convention on Psychotropic Substances.

Bayer is confident that such a meeting would be useful and productive. Our goal is to discuss and form a better understanding of the basis for the WHO recommendation. Given that the criteria under the UN Convention and the WHO recommendation require an assessment of the actual abuse and/or evidence of the likelihood of abuse of an ingredient balanced against such ingredient's usefulness, Bayer would like to present its understanding of the same as it relates to the U.S.

Bayer believes, as stated in the FDA's Federal Register notice, that there are already adequate controls on ephedrine in the U.S. These controls include the U.S. Chemical Diversion and Trafficking Act of 1988, the Domestic Chemical Diversion and Control Act of 1993, the Comprehensive Methamphetamine Control Act of 1996, and the regulations to implement these amendments to the U.S. controlled substances framework. We, therefore, suggest that these controls be examined to determine whether they enable the U.S. to fulfill its obligations under the UN Convention on Psychotropic Substances.

Bayer would welcome the opportunity to provide information on the foregoing and other related matters to assist the FDA in presenting its position on ephedrine at the March, 1999 meeting of the UN Commission on Narcotic Drugs.

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Thank you for your consideration of this request. We at Bayer Corporation look forward to meeting with the FDA.

With best regards,

Bayer Corporation

A handwritten signature in black ink, appearing to read 'Gary S. Balkema', with a stylized, cursive script.

Gary S. Balkema